OCT 24 2003

Kimberly-Clark Corporation

HEALTH CARE SECTOR
1400 Holcomb Bridge Road
Roswell, GA 30076-2199

Phone: (770) 587-8000
Fax: (770) 587-7762

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

[1] 510(k) Summary of Safety and Effectiveness Information

[2] Kimberly-Clark Corporation
1400 Holcomb Bridge Road
Roswell, GA 30076-2199
Telephone: 770-587-8000
Fax: 770-587-7762

Contact: Richard V. Wolfe
Telephone: 770-587-8208
Fax: 770-587-7761

[3] Trade Name: SAFESKIN* BLUE ZONE Powder-Free Vinyl Exam Glove
Common Name: Patient Examination Gloves, Vinyl
Classification Name: Patient Examination Gloves, Vinyl

[4] The predicate device is a Class I, powder-free vinyl exam glove 80LYZ that meets all of the requirements of ASTM D 5250-00, *"Standard Specification for Poly(vinyl chloride) Gloves for Medical Application"*

[5] The powder-free vinyl exam glove meets the current specifications of ASTM D 5250-00, *"Standard Specification for Poly(vinyl chloride) Gloves for Medical Application"*

[6] The powder-free vinyl exam gloves are disposable devices intended to be worn by healthcare and similar personnel to prevent contamination between such personnel and the patient.

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION (Cont'd)

[7] The powder-free vinyl exam gloves possess the following technological characteristics (as compared to ASTM or equivalent standards):

Characteristics	Standards
Dimensions	Meets ASTM D 5250-00
Physical Properties	Meets ASTM D 5250-00
Freedom from pinholes	Meets ASTM D 5250-00 Meets ASTM D 5151-99
Powder Free	Meets ASTM D 6124-01 Meets ASTM D 5250-00

Biocompatibility - Biocompatibility testing was conducted to the following parts of ISO 10993, "Biological Evaluation of Medical Devices":

- Part 10, "Tests for Irritation and Sensitization"
- Part 11, "Tests for Systemic Toxicity(ISO):

Study Title	Test Animal	Results
ISO Skin Irritation Study	Rabbit	Passed
Murine Local Lymph Node Assay (LLNA)	Mouse	Passed
USP and ISO Systemic Toxicity Study Extract	Mouse	Passed

[8] The performance test data that support a determination of substantial equivalence are described above.

[9] Clinical data are not needed for examination gloves.

[10] It can be concluded that the powder-free vinyl exam glove is safe and effective and will perform according to the glove performance standards referenced in Section 7 above, thereby meeting ASTM standards, FDA requirements, and the labeling claims for the product. Consequently, this exam glove is substantially equivalent to currently marketed exam gloves.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 24 2003

Mr. Richard V. Wolfe
Manager, Regulatory Affairs
Kimberly-Clark Corporation
1400 Holcomb Bridge Road
Roswell, Georgia 30076

Re: K031750
Trade/Device Name: SAFESKIN* BLUE ZONE Powder-Free Vinyl Exam Glove
Regulation Number: 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: LYZ
Product Code: I
Dated: August 14, 2003
Received: August 18, 2003

Dear Mr. Wolfe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

Applicant: Kimberly-Clark Corporation

510(k) Number: K031750

Device Name: **SAFESKIN* BLUE ZONE** Powder-Free Vinyl Exam Glove

Indications for Use: Based upon 21CFR§880.6250 "Patient examination glove":

A patient examination glove is a medical device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Patricia Cohen, Division Director, DRCD 10/23/03

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K031750

Prescription Use_____ OR Over-The-Counter _____
Per 21CFR 801.109

Attachment C